

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	MDL No. 1456
LITIGATION)	
<hr/>		CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO)	Judge Patti B. Saris
ALL CLASS ACTIONS)	
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**PLAINTIFFS' MEMORANDUM IN SUPPORT OF ENTRY OF PROPOSED
CASE MANAGEMENT ORDER NO. 8**

Prior to and in the wake of the Court's Memorandum and Order of February 24, 2004 ("*Pharm II*"), plaintiffs have been carefully considering a case management approach that balances the burdens of litigation with the need to advance meaningfully the case against all defendants so that a resolution can occur be it by settlement or trial.

The Rule 12(b)(6) phase of this litigation has concluded, no defendant can escape its duty to now proceed with discovery. In proposed Case Management Order ("CMO") No. 8, plaintiffs propose that the pure AWP aspect of the litigation (excluding Together Rx) proceed in a phased approach pursuant to which discovery and motion practice would proceed on a select number of drugs. Under Phase 1 of that proposal, fact discovery into the "three primary paradigms that accomplish this [AWP] fraud" (*Pharm II*, 4) occurs through discovery of general pharmaceutical industry AWP practices and discovery into approximately one quarter of the drugs specifically identified in the AMCC. The proposed discovery of defendants' marketing, pricing and reimbursement practices, coupled with discovery of the approximately 90 drugs selected by

plaintiffs' counsel and representing a sensible cross-section of fraud paradigms, therapeutic categories and distribution chains, provides the basis to meaningfully examine the next round of factual, procedural (*i.e.*, class) and legal issues. The selected drugs also comprise a meaningful sampling of drugs from each defendant.

In addition, CMO No. 8 addresses several discrete discovery problems that appear to recur in this litigation. In light of the experience to date on the limited discovery that has occurred, the discovery process has demonstrated that without some specific and firm rules in place, a schedule cannot be maintained because the parties do not respond to ongoing discovery notices, requests and obligations in a timely fashion. As a result, plaintiffs propose in CMO No. 8 a set of rules applicable to all parties that are designed to make any schedule the Court sets achievable.

Plaintiffs sent a draft of CMO No. 8 to defendants. Agreement could not be reached on the drugs subject to discovery, on the timing of fact discovery completion, or on the filing of the class certification motion. Defendants did not respond to any of the suggested rules in proposed CMO No. 8.

I. STATUS OF DISCOVERY

A. Discovery Efforts to Date

After the Court issued its order of May 13, 2003 ("*Pharm I*"), plaintiffs served all defendants whom we believed were subject to discovery with requests for production of documents and 30(b)(6) deposition notices.¹ Thereafter, a significant amount of time and energy was expended on the issue of which defendants and drugs were subject to discovery as a result of

¹ The First and Amended requests were served on June 17 and 19, 2003 and the deposition notices on June 17, 2003.

the May 13 Order. Initially, defendants did not formally respond to these requests. Those defendants agreeing to produce documents proposed timetables for doing so that seemed reasonable at the time. Virtually none of the productions occurred when promised. If production had occurred on this timetable, the original March 1 fact cutoff would have been attainable.² Plaintiffs will not burden the Court with the minutiae of production issues, but production responsiveness and timeliness has varied. For example, one defendant promised a full production in the September-October timeframe, received repeated requests concerning the status of the production, and finally produced documents for the first time on January 21, 2004, less than six weeks from the fact discovery cutoff (furthermore, this tardy production is inadequate). Other defendants made their productions in November or December, well after when they had promised to produce, and these productions are also inadequate. Plaintiffs also proceeded with third party subpoenas to the publishers, PBMs, and industry trade associations. The production of documents from these nonparties has been painstakingly slow. Indeed, the PBMs have refused to produce *any* documents, largely because defendants advised them that the scope of discovery is in flux.

B. Post November 21 Discovery

At the November 21, 2003 hearing, the Court ordered that discovery proceed with respect to brand name Part B drugs. Plaintiffs immediately served requests for production of documents with respect to all brand name drugs for which a plaintiff had purchased the drug. Despite the clear indication that discovery was to expand, at least two defendants who manufacture brand name drugs – Amgen and Hoffman – just ignored the Court’s Order and refused to respond.

² Formal responses to the first discovery requests were not received until November, December, 2003 or January 2004.

Plaintiffs assume that the February 24, 2004 Order (“Pharm II”) has resolved that issue as to Amgen.

Other defendants unilaterally narrowed discovery. In their original memorandum regarding this status conference, filed before the Court’s February 24 Order permitting discovery into all drugs, defendants claimed that, if discovery is limited to Medicare Part B drugs, “then issues relating to the reimbursement of Medicare Part B drugs by private payors outside of the Part B context, as well as issues relating to drugs sold through PBMs, would not be subject to discovery.” Defs. Mem. at 6-7.

However, the AMCC alleges that defendants inflate the AWPs for Part B covered drugs both in the Medicare context *and* when third party payors reimburse for those same drugs outside of the Medicare Reimbursement program. AMCC ¶¶ 134, 141, 163, 168-78. In other words, the AMCC not only alleges that defendants’ AWP scheme targets Medicare’s use of AWP as a reimbursement tool, the AMCC also clearly alleges that AWP is used for reimbursement purposes when a drug that happens to be covered by Medicare Part B is used by a non-Medicare patient where the third party payor reimburses directly, or through a PBM, based on AWP. AMCC ¶ 168-78. Thus, this new discovery limitation resulted in no discovery on non Part B covered situations.

II. CASE MANAGEMENT SUGGESTIONS

A. Scope of the Case After Pharm II

As outlined above, since the Court’s ruling in *Pharm I* there has been an ongoing battle over which drugs were subject to discovery. In addition, there were disputes over who was dismissed, which drugs were “Part B drugs,” whether multi-source discovery would proceed, whether discovery was limited to drugs that a plaintiff had purchased, and many other issues

which were not brought to the Court's attention. And recently, as noted above, defendants attempted to limit discovery to brand name drugs in Medicare Part B reimbursement situations only. Plaintiffs drafted CMO No. 8 with the view that *Pharm II* makes it absolutely clear that claims have been sustained on all 321 drugs, that the issues are not limited to Part B reimbursement, and that all defendants are subject to discovery, including those who manufacture multi-source drugs.

B. Suggested Phase Approach

The Court has raised informally at several hearings the idea of using creative techniques to manage discovery and trial in a way that might help the parties evaluate the case without full-blown discovery on all 321 drugs currently targeted in the AMCC. Under plaintiffs' phasing proposal, plaintiffs would select a cross section of drugs from each defendant and have done so in CMO No. 8. The Phase 1 drugs were selected to cover the range of the types of drugs at issue as well as the different reimbursement contexts, including, where applicable for a defendant, generic drugs, Part B and non-Part B drugs, brand name drugs, drugs that are physician administered as well as drugs administered orally. The parties and Court would then set a schedule for discovery, motion practice and trial as to the selected Phase 1 drugs. Such test cases could provide guidance to the parties respecting resolution of claims, or streamline trial, as to the remaining drugs. This approach is recommended by the **MANUAL FOR COMPLEX LITIGATION**, THIRD § 33.28, which discusses innovative approaches such as "bellwether trials on all issues of a limited number of selected cases representative of the total mix, to establish a foundation for resolving the balance." *Id.* at 339. This approach would save the parties significant resources both in terms of party and nonparty discovery.

Defendants' response is to suggest one or two drugs per defendant. The problem with this limited approach is that it is unlikely to lead to resolution. Although AWP abuse/manipulation is a common practice, each defendant had some similar, but also some nuances for implementing the AWP scheme. Plaintiffs need a broad enough cross-section of drugs per defendant to (a) move for class certification; (b) address liability in a meaningful fashion at trial; and (c) intelligently discuss resolution should such talks ever take place.

C. CMO No. 8 Proposed Specific Rules Needed to Meet Any Deadlines and to Have the Litigation Run Smoothly

1. Time Set to Respond to Written Discovery

Proposed CMO No. 8, par. 2, provides as follows:

- a. The parties shall file and serve their initial Phase 1 document requests within seven (7) days of this order.
- b. A responding party to an initial Phase 1 document request shall file and serve their Rule 34(b) written responses within thirty (30) days after service of the request, and each party shall engage in a good faith effort to commence production of the documents at that time.

In the past, defendants have delayed in filing written responses to discovery. These delays then, in turn, delay production. A firm deadline will serve to compel compliance with the case schedule.

2. Prompt Production of 30(b)(6) Witnesses

Proposed CMO No. 8, Section I, par. 5, provides as follows:

5. Each defendant shall if called upon to do so, produce 30(b)(6) witnesses within 45 days of such a request.

In the past, plaintiffs' deposition notices were either ignored or were met with undue delay in obtaining a commitment for production of a witness. To date, despite repeated efforts to do so, not one 30(b)(6) witness has yet been produced. Such depositions are a predicate to streamlining discovery down the road. Without a firm deadline, defendants will drag their feet.

3. Rules on Redaction and Legibility

Proposed CMO No. 8, Sections II.2 and 3, provide as follows:

Defendants have in some instances engaged in heavy redaction, including redaction of the names of drugs that were not yet subject to discovery. Now duplicate productions will have to be made to produce the same documents in unredacted form. This is wasteful and the redaction of documents should be confined to the few circumstances where it is legitimate. Other defendants obscure documents with stamps. *See Exhibit A hereto.*

4. Producing in Electronic Format

Proposed CMO No. 8, Section II.4, provides:

4. Any documents available in an electronic format shall be so provided in that format, *i.e.*, in an identical, usable electronic format. If issues regarding compatibility of computer systems and software arise, the producing party shall contact the other party and resolve those matters.

Defendants are sophisticated companies that manage all of their records electronically. There is no reason for production of documents that are not in an electronic format.

5. Prompt Production of Documents and a Privilege Log

Proposed CMO No. 8, Section II.6 and 7, provides:

6. A responding party to an initial document request shall complete production of all documents within ninety (90) days of service of such request.

7. Privilege logs shall be provided 14 days after a production, and shall cover each document withheld from

production, as well as each redaction from a document produced. A production occurs when a group of documents is provided to another party. A log shall be accompanied by an affidavit(s) sufficient to make a *prima facie* claim of privilege over each document and each redaction withheld from production.

Based on experience to date, document production has been dragging. Five to six months for even the start of production has not been unusual. A standard deadline is imperative if a schedule is to be kept. So far, not one privilege log has been produced. There is no reason for not requiring logs to accompany the production.

6. Prompt Production of Deposition Witnesses

Proposed CMO No. 8, Section II, Par. 8, provides as follows:

8. A party may provide a "three-week deposition notice" under which such party provides at least 21 days notice for a proposed deposition. A responding party may suggest an alternative date no later than seven more days from the original notice. Absent relief obtained from this Court *before* the date for such deposition, a party shall be subject to appropriate discovery sanction(s) for failing to produce the witness on the date, or rescheduled date, for such deposition.

Experience to date indicates that unless the parties have a deadline for producing a witness, intolerable delays confirming a deposition date occurs.

D. Timing of Discovery and Class Certification

Plaintiffs suggest January 7, 2005, as the close of fact discovery. The rest of the dates that flow from that cutoff were largely derived from the intervals that this Court outlined in CMO No. 7. Some additional time was added to account for the added number of drugs and defendants. *See* CMO No. 8 at ¶¶ 1.2 c.-g.

Plaintiffs also suggest a date for the filing of their class certification motion. Plaintiffs believe that they can be in a position to do so by January 1, 2005 and the timing of this motion

and the response and disclosure dates in CMO No. 8 are derived from the schedule set in CMO No. 7. *See Section III.*

E. Other Items the Court Might Want to Consider for Case Management

With discovery about to kickoff, disputes have arisen and will continue to do so. The Court may wish to consider the appointment of a magistrate judge.

The Court may also wish to have monthly telephone calls at which the Court can set briefing schedules, refer issues to the magistrate, resolve issues without briefs, etc. Many courts use this approach in cases of this magnitude.

III. CONCLUSION

Plaintiffs respectfully submit that CMO No. 8 will advance the proper litigation of this case in a meaningful and timely fashion.

DATED: March 5, 2004.

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CERTIFICATE OF SERVICE

I hereby certify that I, Edward Notargiacomo, an attorney, caused true and correct copies of the foregoing Plaintiffs' Memorandum In Support Of Entry Of Proposed Case Management Order No. 8 to be served on all counsel of record electronically, pursuant to Section D of Case Management Order No. 2., this 5th day of March, 2004.

By:


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